K113012 JAN - 5 2012 We are **smith&nephew**

Submitted by:	Smith & Nephew, Inc. 1450 Brooks Road Memphis, Tennessee 38116
Date of Summary:	January 4, 2012
Contact Person:	Megan Bevill, Regulatory Affairs Project Manager T (901) 399-5340 F (901) 566-7086
Name of Device:	Promos Modular Shoulder System
Common Name:	Hemi or Total Shoulder
Device Classification Name and Reference:	21 CFR 888.3690 Prosthesis, shoulder, hemi-, humeral, metallic uncemented – Class II 21 CFR 888.3660 Prosthesis, shoulder, semi-constrained, metal/polymer cemented – Class II
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSD, KWS

Device Description

The Promos Modular Shoulder System, as cleared via premarket notification K063578, consists of two primary components: the glenoid component and the modular humeral component. The modular humeral component consists of a distal stem, body, inclination set, and humeral head. Subject of this premarket notification is a review of changes to the Promos inclination set. No changes will be made to the glenoid, humeral head, body, or distal stem as a result of this premarket notification. Modifications to the inclination set components are intended to increase the overall strength and stability of the construct. The design concept remains the same, and the inclination set continues to mate with the humeral head and proximal body in the same way.

The modified devices consist of three components: internal cone, sleeve, and set screw. The subject inclination sets are manufactured from Ti-6Al-4V material conforming to ISO 5832-3 and are available in four sizes.

Technological Characteristics

A review of the mechanical data indicates that the Promos Modular Shoulder System is capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the Promos Modular Shoulder System was performed:

- Static testing of set screw
- Pre-fatigue taper strength
- Construct fatigue, including post-fatigue taper evaluations

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

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Intended Use
The Promos Modular Shoulder System is indicated for:

- Advanced degeneration of the shoulder joint as a results of degenerative, post-traumatic or inflammatory arthritis
- Avascular necrosis of the humeral head
- Complex fractures of the proximal humerus
- Functional impairment especially in the case of post-traumatic loss of the joint configuration

The humeral component is intended for cemented or cementless use. The glenoid component is for use with bone cement only.

Substantial Equivalence Information
The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the Promos Modular Shoulder System Inclination Sets cleared via premarket notification K063578. They are also similar in intended use to the Cofield 2 Shoulder System cleared via premarket notification K955767.

Table 1: Substantially equivalent predicate devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG (former Plus Orthopedics AG)	Promos Modular Shoulder System	K063578	3/2/2007
Smith & Nephew, Inc.	Cofield 2 Shoulder System	K955767	4/8/1996

Conclusion
As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the modified Inclination Sets of the Promos Modular Shoulder System. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate shoulder system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 5 2012

Smith & Nephew, Incorporated
% Ms. Megan Bevill
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis Tennessee 38116

Re: K113012
Trade/Device Name: Promos Modular Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: October 7, 2011
Received: October 11, 2011

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113012

Indications for Use

510(k) Number (if known): _____

Device Name: Promos Modular Shoulder System

The Promos Modular Shoulder System is indicated for:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113012